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Participant Information sheet

Subcutaneous Injection of Adalimumab Trial Compared with Control (SCIATiC)

A randomised controlled trial of adalimumab injection compared with placebo for patients receiving physiotherapy treatment for sciatica

Part 1

Introduction

We would like to invite you to take part in the SCIATiC research trial. Before deciding if you want to take part, it is important that you understand why we are doing this trial and what it will involve for you. Please take the time to read this information sheet carefully and talk to others (such as friends and family) about it if you wish.

Ask us if there is anything that you don't understand or if you need more information.

Part 1 tells you about the study and what will happen if you take part

Part 2 gives you more detailed information about how the study is conducted.

What is the purpose of the SCIATiC trial?

Sciatica is the name given to the pain caused by irritation or compression of the sciatic nerve root. The sciatic nerve runs from the back of your pelvis, through your buttocks, and all the way down both legs, ending at your feet. When a prolapsed disc irritates the sciatic nerve, it can cause pain that spreads out from your lower back and travels down your leg to your calf and often foot and toes. Sciatic pain can range from being mild to very painful. It is often associated with numbness or a pins and needles sensation.

Typical care involves the prescribing of pain relief (pain killers) or anti-inflammatory medication by your GP, and if troublesome symptoms persist, referral for physiotherapy. If pain persists patients are referred for more invasive treatment such as injections into the spine and eventually surgery. At present between 5-15% of patients with sciatica eventually need surgery.

Adalimumab is a drug given to people who suffer from inflammatory disease like rheumatoid arthritis. Adalimumab may have beneficial effects on the inflamed nerve root in sciatica. It is given by an injection under the skin in a hospital out-patient clinic.

The aim of this research is to find out how effective injections of adalimumab in conjunction with physiotherapy are, compared with an injection of saline (placebo-this a dummy treatment which looks like the real thing but is not. It contains no active ingredient) plus physiotherapy for patients with sciatica whose pain is troublesome and persistent despite treatment from their GP. 332 participants will be recruited from primary care or musculoskeletal services from five collaborating centres within the UK.

Why have I been chosen to take part?

You have been invited to take part as your sciatica persists and is troublesome despite treatment from your GP.

Do I have to take part?

No, participation in this trial is totally voluntary. If you decide to take part you will be asked to sign a consent form and be given a copy of the form to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the treatment or care that you receive in anyway.

What will I be asked to do if I decide to take part?

Your GP or a clinician from your local musculoskeletal services has looked at your medical records to see if you might be eligible, and has sent you this information sheet about the trial to ask if you are interested in taking part in this research. If you are interested in participating please either email, telephone the research team at (insert local email address), (local telephone number), or return the acceptance form in the freepost envelope provided. You will then be contacted by telephone by the research physiotherapist or a qualified member of the research team.to confirm that you are eligible and happy to continue. If so, you will be sent an appointment to attend the SCIATiC research clinic.

At the first assessment at the SCIATiC research clinic, the physiotherapist or a qualified member of the research team. will tell you all about the trial, check if you are eligible to take part and answer any questions you have about it. Should you wish to take part you will be asked to complete the consent form and will be given a copy of your consent form and this information leaflet to keep. A copy of the consent form that will be used is included with this information sheet. You will then be registered onto the trial. Three copies of the consent form will be signed, the original will be kept by the research team, the second copy will be given to you and the third copy will be filed in your medical notes.

Within two to three weeks of the first assessment visit you will be sent for a routine blood test, pregnancy urine test for women, tuberculosis (TB) screening including a chest X-ray, a research nurse will fully brief you about the adalimumab drug; and a magnetic resonance imaging (MRI) scan to exclude any serious spinal problem.

After two to three weeks from your first assessment you will need to attend a second assessment at the SCIATiC research clinic to determine if you are still eligible and confirm that all required assessments have been performed and are satisfactory. You will sign a final consent form taken by a rheumatologist, complete a questionnaire, which will take approximately 20 minutes to complete, asking about your sciatica pain and how it affects your health and then entered into the trial.

You will be given injections two weeks apart. In order to decide which injection you will receive, a computer programme will randomly allocate you to one of either the adalimumab injection group or the placebo. This means that neither you nor the research physiotherapist nor the research team know which group you are in (however, if there is a need during the trial to know then the research team can find out). In order to make a fair comparison, half of the patients taking part in the trial will receive the adalimumab injection and the other half will receive the placebo injection. You will have an equal chance of receiving adalimumab or placebo saline (placebo) injections. The injections will be prescribed by a consultant rheumatologist and administered by a rheumatology specialist nurse experienced in the administration of these injections. The first injections will be given on the same day you are randomised into the trial. You will also be given an appointment to return two weeks later for your last injection. Both groups will also attend a course of physiotherapy which will consist of a package of treatment including exercises designed for patients with sciatica. If your symptoms have settled after this treatment you will be referred back to your GP. If your symptoms persist then you will be referred to the spinal clinic

Follow-up questionnaires which will take approximately 20 minutes to complete will also be sent to you in the post after six weeks, six months and twelve months. They will contain a free post envelope for you to return them. You will receive message alerts prior to questionnaires being sent out and regular newsletters notifying you when questionnaires have been sent. Two weeks after the last questionnaire has been sent you will be contacted by a member of the research team. They will ask you about your overall experience of the trial and follow-up treatment as well as asking which treatment group you think you were in.

Will I be reimbursed for participating in the trial?

You can claim back your travel expenses for getting to and from the hospital (please keep your receipts or tickets, and show them to the study research team).

What are the drugs being tested?

Adalimumab has been prescribed in the UK for a number of years to people who suffer from inflammatory disease like rheumatoid arthritis. It is one of the groups of drugs known as monoclonal antibodies (MAB); MABs are a type of biological therapy. Adalimumab may have beneficial effects on the inflamed nerve root in sciatica as it is an anti-TNF drugs which block the action of TNF and so reduce this inflammation. It is given by an injection under the skin in a hospital out-patient clinic.

What are the alternatives?

Physiotherapy is usually considered normal practice for those participants that fail to improve with GP care.

What are the possible disadvantages and risks of taking part?

The trial generally follows the normal physiotherapy treatment but with some newer treatments added to see if they are of benefit. You should not be disadvantaged by entering the study. However, you will need to attend the research clinic at the following time points:-

- First assessment - check eligibility, if found to be eligible initial consent and registered onto the trial. Sent for routine bloods, Urine pregnancy test if female, TB testing and biological counselling about the drug, MRI.
- Second assessment – results of blood test, TB testing and MRI checked to confirm eligibility, final consent form completed, baseline questionnaire completed, allocated to treatment group at random. You will receive the first injection at this visit.
- Third Assessment – The second injection will be given.

You will also be referred for physiotherapy at your local physiotherapy department. This will be up to six treatments over a period of twelve weeks determined by participant and therapist preference and also response to treatment. We will capture and describe these aspects of physiotherapy treatment as part of the trial. Your physiotherapy treatment should preferably start at the same week as your first injection. You will not receive any other NHS-based co-intervention until this physiotherapy treatment has finished.

Adalimumab has known side-effects. These will be discussed with you at the start of the trial by the rheumatology specialist nurse, but we have a great deal of experience in using it safely for illnesses like rheumatoid arthritis. The most common side-effects are reactions at the injection site, such as redness, swelling or pain. These reactions aren't usually serious.

Adalimumab affects the immune system (the body's own defence system), so you may be more likely to develop infections. At the same time, adalimumab can mask the symptoms of infection so you may not feel as ill as you normally would when you do have an infection.

You should tell your research physiotherapist or rheumatology specialist nurse straight away if you develop any of the following after starting adalimumab:

- a sore throat
- a fever
- any other symptoms of infection
- any other new symptoms or anything else that concerns you.

In order to use it safely, participants will receive screening for TB and counselling about its effects from nurses experienced in its use. Part of the TB testing is to undergo as chest x-ray. X-rays are a type of radiation known as ionising radiation. The dose that you get from a medical x-ray is very low and the associated risks are minimal. They are similar in strength to other sources of natural radiation that people are exposed to everyday without even realising it. The radiographer is responsible for making sure that your dose is kept as low as possible and that the benefits of having the x-ray outweigh any risk. You will also undergo an MRI. This is a very safe procedure for most patients. However, patients with heart pacemakers and certain other surgical implants, for example a cochlear implant, cannot be scanned. You will be asked to complete and sign a safety questionnaire before your scan to make sure it is safe for you to be scanned.

If you are, or think you may be pregnant you must tell a member of staff in the radiology department knows as soon as possible. The radiation in an X-ray can be harmful for an unborn baby and MRI scans are not advisable in early pregnancy unless there are special circumstance

Like all drugs the adalimumab may have side-effects that we don't know about yet. This is unlikely because it is being used to treat patients throughout the NHS. However, you should report anything out of the ordinary or that may concern you to the research physiotherapist or rheumatology specialist nurse in case it represents a potential side-effect. All side-effects are reported to the study organisers in Bangor University who will keep a very close watch on any problems that might develop. Similarly, all effects and benefits are confidentially reviewed by an independent group of doctors who are not involved with the study at all. This is to ensure that any problems are rapidly identified and acted upon.

It is important that women of child-bearing age do not become pregnant while on this trial as the effects of these treatments on the foetus are unknown. Pregnant women must not take part in this study, and women should not plan to become pregnant during the study. A urine pregnancy test will be performed as part of the screening assessment to exclude the possibility of pregnancy. Women who could become pregnant must use an effective

contraceptive during the course of this study or for a safety period of five months after the last injection. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor.
It is not known if the study medicine will affect sperm or semen and therefore you should not father a child during this study or for a safety period of five months after the last injection.
If your partner might become pregnant you must use reliable forms of contraception during the trial and for five months afterwards. If your partner becomes pregnant during the study or within five months of stopping treatment, you should inform your study doctor immediately.
Should you or your partner fall pregnant during the trial the need for additional medical supervision will be discussed with you.

What are the possible benefits of taking part?

You will receive physiotherapy treatment in addition to the injections, for your sciatic pain. Physiotherapy is often used for patients with sciatica and there is evidence to suggest that it helps a number of them. We hope that you will benefit from the physiotherapy treatment. We do not know whether you will benefit from the injections, but we hope that the information we get from the trial results will help to improve the treatment option for patients with sciatica

What else should I know about adalimumab?

It is recommended that you carry a biological therapy alert card, which you can get from your doctor or rheumatology nurse. Then if you become unwell, anyone treating you will know that you're on the SCIATiC trial and that you are therefore at risk of its side-effects, including infections.

Can I take other medicines alongside adalimumab?

Adalimumab may be prescribed alongside other drugs. You should discuss any new medications with your doctor before starting them, and you should always tell any other doctor treating you that you are on adalimumab. You should also be aware of the following points:

- Adalimumab is not a painkiller. If you are already on painkillers or anti-inflammatory medication you can carry on taking these as well as adalimumab, unless your doctor

advises otherwise. If adalimumab works for you, you may be able to reduce painkillers or anti-inflammatory after a time.

- Do not take over-the-counter preparations or herbal remedies without discussing this first with your research physiotherapist, rheumatology nurse or pharmacist.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to one of your local study team or to the trial organisers. The Chief Investigator for the whole study is Dr Nefyn Williams. The principal investigator for the North Wales centre is Professor Clare Wilkinson. If you think you have suffered harm or negligence, you may complain through your local hospital complaints procedure or you may have grounds for a legal action against the trial sponsor which is Bangor University.
Detailed information about this is given in Part 2.

Will my taking part in this study be kept confidential?

All information collected in this study will be kept strictly confidential. Only members of the research team will have access to it. Each person who consents to take part in the trial will be given a unique code number so no names or details identifying specific individuals will be used on questionnaires or included in any study reports. This means that the data is anonymous. If you consent to take part in the research, your medical records may be inspected by the hospital personnel or the Chief Investigator or his nominee on behalf of the trial Sponsor who is Bangor University for purposes of analysing the results. Your GP will be informed, with your consent that you wish to take part in a clinical study

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This completes Part 1. If you are interested in the study, please read the additional information in Part 2 before making any decision.



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Patient Information

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Part 2

What if new information becomes available?

As the study progresses, new information about the treatments or results may become available. If this happens, we will tell you and discuss what it means for you. It may mean that you should withdraw from the study and your doctor will explain this if need be. Your doctor will continue your treatment using the best treatments available.

What will happen if I don't want to carry on with the study?

If you decide not to continue the trial for any reason, you should discuss this with your doctor. You are free to withdraw at any time, but it is best to let your doctor know so that they can make the best arrangements to ensure the treatment of your sciatica continues in the best way possible. If you withdraw, we will still need to use the information we have

collected about the treatment you were given and how well you did, up to the time you withdraw. You can also withdraw from the trial, but still allow us to tell the study organisers from time to time how well you are doing.

What happens if something goes wrong?

We believe that this study is safe and we do not expect you to suffer any harm or injury because of your participation in it. The NHS indemnity scheme will compensate you if you are harmed due to someone's negligence but there is no compensation scheme for harm that was not caused by negligence. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study, the normal National Health Service complaints mechanisms will be available to you. However, we would ask you first to speak to one of the research team, so that we can try to address your concerns and find a solution. You can talk to the local researcher (*insert local contact details*) or you can contact the Chief Investigator, Dr Nefyn Williams (contact details removed Telephone: Contact details removed E-mail: Contact details removed If you are not satisfied with our response you can make a complaint to the trial sponsor which is Bangor University Mrs Gwenan Hine, contact details removed tel Contact details removed

What will happen to the results of the research study?

Results from this trial will be presented at regional national and international meetings where interested doctors, therapists, specialist nurses and health service commissioners would be present. In addition to preparing an article for the Health Technology series, papers will be submitted to relevant international journals such as Spine, Spine Journal, British Medical Journal and Lancet. The results will be distributed to policy makers, advisory groups and professional bodies, for example the Welsh Government, the National Strategic Advisory Group (NSAG), and National Institute for Health and Care Excellence (NICE). The university also disseminates information on projects and results in articles on the Advances Wales publication, and as Bangor University is a member of MediWales, can take advantage of this network for further opportunities to disseminate the results.

We will also communicate the key results to participant support groups, for example so that findings that could benefit participants with sciatica can be disseminated to affected participant groups. In particular we will contact Back Care the charity for healthier backs to use their Back Care Journal and Talkback magazine, Pain Concern through their Pain Matters magazine, as well as Arthritis Research UK through its magazine Arthritis Today and on-line patient materials.

Who is organising and funding the research?

We have obtained a grant from the National Institute for Health Research. The Chief Investigator is Dr Nefyn Williams from Bangor University and his team includes researchers, doctors and other health professionals from Bangor University and the Betsi Cadwaladr University Health Board. The Lead Investigator for the North Wales centre is Professor Clare Wilkinson.

What should I do if I have any concerns about the study?

If you have any concerns about the study, please contact the Chief Investigator in the first instance.

Dr Nefyn Williams
Chief Investigator, SCIATiC

Dr Clare Wilkinson
Lead Investigator, SCIATiC

There is also a lead person at your local institution. In the case of (CENTRE), that is (PERSON) who can be contacted on (TELEPHONE)

What do I do now?

If you agree to take part in the study a research physiotherapist or a qualified member of the research team will be contacting you to see if you might be eligible, and if you are, will give you an appointment to see you in a research clinic

This completes Part 2. If you have any further questions, please ask a member of your local study team. If you are happy to take part in the study, you team will ask you to complete the attached consent form. You will be able to keep a copy of this.

Thank you

Please keep this information sheet for your records

If you agree to enter the study.

Nodwch bennyn lleol

Taflen Wybodaeth i Gyfranogwyr

Treial Pigiad Isgroenol o Adalimumab o'i Gymharu â Rheolydd (SCIATiC)

Treial dan reolaeth ar hap o bigiad adalimumab o'i gymharu â phlasebo ar gyfer cleifion sy'n cael triniaeth ffisiotherapi ar gyfer clunwst

Rhan 1

Cyflwyniad

Hoffem eich gwahodd i gymryd rhan yn nhreial astudiaeth SCIATiC. Cyn penderfynu a ddymunwch gymryd rhan, mae'n bwysig eich bod yn deall pam ein bod yn cynnal y treial hwn a beth fydd yn ei olygu i chi. Rhowch o'ch amser i ddarllen y daflen wybodaeth hon yn ofalus a siaradwch â phobl eraill (fel teulu a ffrindiau) amdano os dymunwch.

Gofynnwch i ni os oes unrhyw beth nad ydych yn ei ddeall neu os oes angen mwy o wybodaeth arnoch.

Mae Rhan 1 yn dweud wrthych am yr astudiaeth a beth fydd yn digwydd os byddwch yn cymryd rhan

Mae Rhan 2 yn rhoi gwybodaeth fwy manwl i chi am sut fydd yr astudiaeth yn cael ei chynnal.

Beth yw diben y treial SCIATiC?

Clunwst (sciatica) yw'r enw a roddir i'r boen a achosir gan lid neu gywasgiad gwreiddyn y nerf siatig. Mae'r nerf siatig yn rhedeg o gefn eich pelfis, trwy eich ffolennau, a'r holl ffordd i lawr y ddau goes, gan orffen yn eich traed. Pan fydd disg wedi llithro o'i le yn llidio'r nerf siatig, gall achosi poen sy'n lledaenu o ran isaf eich cefn ac yn teithio i lawr eich coes i'ch croth coes ac yn aml i'ch troed a bysedd y troed. Gall poen siatig amrywio o ysgafn i boenus iawn. Yn aml mae'n gysylltiedig â fferdod neu deimlad pinnau bach.

Mae gofal nodweddiadol yn golygu cyffuriau lleddfu poen neu feddyginiaeth wrthlidiol ar bresgripsiwn gan eich Meddyg Teulu, ac os bydd symptomau trafferthus yn parhau, atgyfeiriad ar gyfer ffisiotherapi. Os bydd poen yn parhau, bydd cleifion yn cael eu hatgyfeirio ar gyfer triniaeth mwy mewnwthiol fel pigiadau i'r asgwrn cefn a llawdriniaeth yn y pen draw. Ar hyn o bryd, mae 5-15% o gleifion â chlunwst angen llawdriniaeth yn y pen draw.

Cyffur yw adalimumab sy'n cael ei roi i bobl sy'n dioddef gan glefyd llidiol fel arthritis gwynegol. Efallai bod adalimumab yn cael effeithiau buddiol ar wreiddyn y nerf llidiol mewn clunwst. Mae'n cael ei roi trwy bigiad o dan y croen mewn clinig cleifion allanol mewn ysbyty.

Nod yr ymchwil hwn yw darganfod pa mor effeithiol y mae pigiadau adalimumab ar y cyd â ffisiotherapi, o'u cymharu â phigiad o doddiant halwyn (plasebo - dyma driniaeth ffug sy'n edrych fel y driniaeth go iawn ond nid dyma ydyw. Nid yw'n cynnwys unrhyw gynhwysyn gweithredol) yn ogystal â ffisiotherapi i gleifion â chlunwst â phoen sy'n drafferthus er gwaethaf triniaeth eu meddyg teulu. Bydd 332 o gyfranogwyr yn cael eu recriwtio o wasanaethau gofal sylfaenol neu gyhyrysgerbydol o bum canolfan sy'n cydweithredu yn y DU.

Pam ydw i wedi cael fy newis i gymryd rhan?

Rydych chi wedi cael eich dewis i gymryd rhan oherwydd bod eich clunwst yn parhau ac mae'n drafferthus er gwaethaf triniaeth eich meddyg teulu.

A oes yn rhaid i mi gymryd rhan?

Nac oes, mae cyfranogiad yn y treial hwn yn hollol wirfoddol. Os penderfynwch gymryd rhan bydd gofyn i chi lofnodi ffurflen gydsyniad a byddwch yn cael copi o'r ffurflen i'w gadw. Os byddwch yn penderfynu cymryd rhan byddwch yn dal i fod yn rhydd i dynnu'n ôl ar unrhyw adeg a heb roi rheswm. Os byddwch yn penderfynu tynnu'n ôl ar unrhyw adeg, neu'n

penderfynu peidio â chymryd rhan, ni fydd hynny'n effeithio ar eich triniaeth neu ofal mewn unrhyw ffordd.

Beth fydd gofyn i mi wneud os byddaf yn penderfynu cymryd rhan?

Mae eich meddyg teulu neu glinygydd o'ch gwasanaethau cyhyrysgerbydol lleol wedi edrych ar eich cofnodion meddygol i weld a allech fod yn gymwys, ac wedi anfon y daflen wybodaeth hon atoch ynglŷn â'r treial i ofyn a oes gennych ddiddordeb mewn cymryd rhan yn yr ymchwil hwn. Os oes gennych ddiddordeb mewn cymryd rhan, e-bostiwch, ffoniwch y tîm ymchwil yn (nodwch gyfeiriad e-bost lleol), (rhif ffôn lleol), neu dychwelwch y ffurflen dderbyn yn yr amlen rhadbost a ddarparwyd. Yna bydd y ffisiotherapydd ymchwil neu aelod cymwysedig o'r tîm ymchwil yn cysylltu â chi dros y ffôn i gadarnhau eich bod yn gymwys ac yn hapus i barhau. Os felly, bydd apwyntiad yn cael ei anfon atoch i fynychu clinig ymchwil SCIATiC.

Yn yr asesiad cyntaf yng nghlinig ymchwil SCIATiC, bydd y ffisiotherapydd neu aelod cymwysedig o'r tîm ymchwil yn dweud popeth wrthych am y treial, yn gwirio a ydych yn gymwys i gymryd rhan ac yn ateb unrhyw gwestiynau a allai fod gennych amdano. Os dymunwch gymryd rhan bydd gofyn i chi gwblhau'r ffurflen gydsyniad a byddwch yn cael copi o'ch ffurflen gydsyniad a'r daflen wybodaeth hon i'w cadw. Mae copi o'r ffurflen gydsyniad a ddefnyddir wedi'i gynnwys â'r daflen wybodaeth hon. Yna byddwch wedi cofrestru ar y treial. Bydd tri chopi o'r ffurflen gydsyniad yn cael eu llofnodi, bydd y tîm ymchwil yn cadw'r copi gwreiddiol, byddwch chi'n cael yr ail gopi a bydd y trydydd copi'n cael ei ffeilio yn eich nodiadau meddygol.

Cyn pen dwy neu dair wythnos o'r ymweliad asesu cyntaf byddwch yn cael eich anfon am brawf gwaed fel mater o drefn, prawf wrin beichiogrwydd i ferched, sgrinio twbercwlosis (TB) gan gynnwys pelydr-X o'r frest, bydd nyrs ymchwil yn darparu gwybodaeth lawn i chi am y cyffur adalimumab; a sgan delweddu atseiniol magnetig (MRI) i sicrhau nad oes unrhyw broblemau sbinol difrifol.

Dwy neu dair wythnos ar ôl eich asesiad cyntaf bydd angen i chi fynychu ail asesiad yng nghlinig ymchwil SCIATiC i bennu a ydych yn parhau i fod yn gymwys a chadarnhau bod yr holl asesiadau gofynnol wedi cael eu cynnal ac yn foddhaol. Bydd angen i chi lofnodi ffurflen gydsyniad terfynol wedi'i chymryd gan riwmatolegydd, llenwi holiadur, y bydd yn cymryd oddeutu 20 munud i'w lenwi, gofyn am eich poen clunwst a sut mae'n effeithio ar eich iechyd ac yna byddwch yn ymuno â'r treial.

Byddwch yn cael pigiadau â phythefnos rhyngddynt. Er mwyn penderfynu pa bigiad byddwch yn ei gael, bydd rhaglen gyfrifiadur yn eich dyrannu ar hap i naill a'r grŵp pigiad

adalimumab ynteu'r grŵp plasebo. Mae hyn yn golygu na fyddwch chi na'r ffisiotherapydd ymchwil a'r tîm ymchwil yn gwybod i ba grŵp rydych yn perthyn (fodd bynnag, os bydd angen darganfod hyn yn ystod y treial, yna gall y tîm ymchwil ddarganfod hyn). Er mwyn gwneud cymhariaeth deg, bydd hanner y cleifion sy'n cymryd rhan yn y treial yn cael y pigiad adalimumab a bydd yr hanner arall yn cael y pigiad plasebo. Bydd gennych siawns cyfartal o gael pigiadau adalimumab neu doddiant halwyn plasebo (plasebo). Bydd rhiwmatolegydd ymgynghorol yn rhoi'r pigiadau ar bresgripsiwn a bydd nyrs arbenigol rhiwmatoleg sy'n brofiadol o ran rhoi'r pigiadau hyn yn eu rhoi. Byddwch yn cael y pigiadau cyntaf ar yr un diwrnod ag y byddwch yn ymuno â'r treial ar hap. Hefyd byddwch yn cael apwyntiad i ddychwelyd pythefnos yn ddiweddaraf ar gyfer eich pigiad olaf. Bydd y ddau grŵp hefyd yn mynychu cwrs o ffisiotherapi a fydd yn cynnwys pecyn o driniaeth sy'n cynnwys ymarferion corff a ddyluniwyd i gleifion â chlunwst. Os bydd eich symptomau wedi gwella ar ôl y driniaeth hon byddwch yn cael ei atgyfeirio'n ôl i'ch meddyg teulu. Os bydd eich symptomau'n parhau yna byddwch yn cael ei atgyfeirio i'r clinig sbinol

Hefyd bydd holiaduron dilynol, a fydd yn cymryd oddeutu 20 munud i'w llenwi, yn cael eu hanfon atoch yn y post ar ôl chwe wythnos, chwe mis a deuddeg mis. Byddant yn cynnwys amlen rhadbost er mwyn i chi eu dychwelyd. Byddwch yn cael negeseuon rhybuddio cyn i holiaduron gael eu hanfon atoch a chylchlythyrau rheolaidd yn rhoi gwybod i chi pan fydd holiaduron wedi cael eu hanfon. Bythefnos ar ôl i'r holiadur olaf gael ei anfon bydd aelod o'r tîm ymchwil yn cysylltu â chi. Bydd ef/hi'n gofyn i chi am eich profiad cyffredinol o'r treial a thriniaeth ddilynol yn ogystal â gofyn i ba grŵp triniaeth ydych chi'n meddwl eich bod yn perthyn.

A fyddaf yn cael fy ad-dalu am gymryd rhan yn y treial?

Gallwch ad-hawlio eich costau teithio am gyrraedd yr ysbyty a mynd yn ôl adref (cadwch eich derbynebau neu docynnau, a dangoswch y rhain i dîm ymchwil yr astudiaeth).

Pa gyffuriau sy’n cael eu rhoi ar brawf?

Mae adalimumab wedi cael ei roi ar bresgripsiwn ers nifer o flynyddoedd i bobl sy'n dioddef gan glefyd llidiol fel arthritis gwynegol. Mae'r perthyn i'r grwpiau o gyffuriau o'r enw gwrthgyrff monoclonaidd (MAB); mae MABs yn fath o therapi biolegol. Efallai y bydd adalimumab yn cael effeithiau buddiol ar wreiddyn y nerf sy'n llidiol mewn clunwst oherwydd ei fod yn gyffur gwrth-TNF sy'n rhwystro gweithrediad TNF ac felly'n lleihau'r llid hwn. Mae'n cael ei roi trwy bigiad o dan y croen mewn clinig cleifion allanol mewn ysbyty.

Beth yw'r dewisiadau amgen?

Fel arfer ystyrir ffisiotherapi fel ymarfer normal ar gyfer y cyfranogwyr hynny sy'n methu â gwella â gofal meddyg teulu.

Beth yw anfanteision a risgiau posibl cymryd rhan?

Yn gyffredinol mae'r treial yn dilyn y driniaeth ffisiotherapi normal ond â rhai triniaethau mwy newydd wedi'u hychwanegu i weld a ydynt o fudd. Ni ddylech fod o dan anfantais trwy ymuno â'r astudiaeth. Fodd bynnag, bydd angen i chi fynychu'r clinig ymchwil ar y pwyntiau amser canlynol:-

- Asesiad pellach - gwirio cymhwysedd, os darganfyddir eich bod yn gymwys, cydsyniad cychwynnol a chofrestru ar y treial. Anfon am brofiad gwaed fel mater o drefn, Prawf wrin beichiogrwydd os yn fenywaidd, profion TB a chwnsela ynglŷn â'r cyffur, MRI.
- Ail asesiad - canlyniadau prawf gwaed, profion TB a gwirio MRI i gadarnhau cymhwysedd, llenwi ffurflen gydsyniad terfynol, llenwi holiadur gwaelodlin, dyrannu i grŵp triniaeth ar hap. Byddwch yn derbyn y pigiad cyntaf yn yr ymweliad hwn.
- Trydydd Asesiad - Bydd yr ail bigiad yn cael ei roi.

Byddwch hefyd yn cael eich atgyfeirio ar gyfer ffisiotherapi yn eich adran ffisiotherapi leol. Bydd hyd at chwe thriniaeth dros gyfnod deuddeg wythnos wedi'i bennu gan ddewisiadau'r cyfranogwr a'r therapydd yn ogystal â'r ymateb i driniaeth. Byddwn yn casglu ac yn disgrifio'r agweddau hyn ar driniaeth ffisiotherapi fel rhan o'r treial. Yn ddelfrydol dylai'ch triniaeth ffisiotherapi ddechrau yn yr un wythnos â'ch pigiad cyntaf. Ni fyddwch yn derbyn unrhyw gyd-ymyrraeth arall gan y GIG nes bod y driniaeth ffisiotherapi hon wedi gorffen.

Mae gan adalimumab sgil-effeithiau hysbys. Bydd y nyrs arbenigol rhiwmatoleg yn trafod y rhain â chi ar ddechrau'r treial, ond mae gennym lawer o brofiad o'i ddefnyddio'n ddiogel ar gyfer afiechydon fel arthritis gwynegol. Y sgil-effeithiau mwyaf cyffredin yw adweithiau yn safle'r pigiad, fel cochni, chwydd neu boen. Fel arfer nid yw'r adweithiau hyn yn ddifrifol.

Mae adalimumab yn effeithio ar y system imiwnedd (system amddiffyn y corff), felly efallai y byddwch yn fwy tebygol o ddatblygu heintiau. Ar yr un adeg, gall adalimumab guddio symptomau haint fel efallai na fyddwch yn teimlo mor sâl ag y byddech fel arfer pan fydd gennych haint.

Dylech ddweud wrth eich ffisiotherapydd ymchwil neu nyrs arbenigol rhiwmatoleg ar unwaith os byddwch yn datblygu unrhyw un neu rai o'r symptomau canlynol ar ôl dechrau ar adalimumab:

- dolur gwddf
- twymyn
- unrhyw symptom arall o haint
- unrhyw symptomau eraill newydd neu unrhyw beth arall sy'n achos pryder i chi.

Er mwyn ei ddefnyddio yn ddiogel, bydd cyfranogwyr yn cael eu sgrinio ar gyfer TB a'u cwnsela am ei effeithiau gan nyrsys sy'n brofiadol yn ei ddefnydd. Rhan o'r profion TB yw ymgymryd â phelydr-x o'r frest. Math o ymbelydredd yw pelydr-x sy'n cael ei alw'n ymbelydredd ïoneiddio. Bydd y dos a gewch o belydr-x meddygol yn isel iawn ac mae'r risgiau sy'n gysylltiedig â hyn yn fach iawn. Maent yn debyg o ran cryfder i ffynonellau eraill o ymbelydredd naturiol bydd pobl yn agored iddynt bob dydd heb hyd yn oed sylweddoli. Mae'r radiograffydd yn gyfrifol am wneud yn siŵr bod y dos yn cael ei gadw mor isel â phosibl a bod buddion cael y pelydr-x yn gorbwyso unrhyw risg. Byddwch hefyd yn cael MRI. Dyma weithred ddiogel iawn i'r rhan fwyaf o gleifion. Fodd bynnag, ni fydd cleifion â rheolyddion calon a rhai mathau eraill o fewnblaniadau llawfeddygol, er enghraifft, mewnblaniad cochleaidd, yn gallu cael eu sganio. Bydd gofyn i chi lenwi a llofnodi holiadur diogelwch cyn eich sgan i wneud yn siŵr ei bod yn ddiogel i chi gael eich sganio.

Os ydych chi'n feichiog, neu'n meddwl y gallech fod yn feichiog, mae'n rhaid i chi roi gwybod i aelod o staff yn yr adran radioleg cyn gynted â phosibl. Gall yr ymbelydredd mewn pelydr-X fod yn niweidiol i fabi yn y groth ac ni chynghori sganiau MRI yn ystod beichiogrwydd cynnar oni bai bod amgylchiadau arbennig

Fel pob cyffur, efallai y bydd adalimumab yn achosi sgil-effeithiau nad ydynt eto'n hysbys i ni. Mae hyn annhebygol oherwydd ei fod yn cael ei ddefnyddio i drin cleifion yn y GIG drwyddo draw. Fodd bynnag, dylech roi gwybod i ffisiotherapydd yr ymchwil neu'r nyrs arbenigol rhiwmatoleg am unrhyw beth anarferol neu unrhyw beth a allai achosi pryder i chi, rhag ofn ei fod yn cynrychioli sgil-effaith bosibl. Adroddir i drefnwyr yr ymchwil ym Mhrifysgol Bangor am bob sgil-effaith, a byddant yn cadw golwg agos iawn ar unrhyw broblemau a allai ddatblygu. Yn debyg, bydd yr holl effeithiau a buddion yn cael eu hadolygu yn gyfrinachol gan grŵp annibynnol o feddygon nad ydynt yn gysylltiedig â'r astudiaeth. Nod hyn yw sicrhau bod unrhyw broblemau'n cael eu nodi'n gyflym a gweithredir arnynt yn gyflym.

Mae'n bwysig na fydd merched o oedran cario plant yn dod yn feichiog tra byddant yn rhan o'r treial hwn oherwydd bod effeithiau'r triniaethau hyn ar y ffetws yn anhysbys. Ni chaniateir i ferched beichiog gymryd rhan yn yr astudiaeth hon, ac ni ddylai merched gynllunio dod yn feichiog yn ystod yr astudiaeth. Bydd prawf wrin beichiogrwydd yn cael ei gynnal fel rhan o'r asesiad sgrinio i sicrhau nad oes posibilrwydd o feichiogrwydd. Mae'n rhaid i ferched a allai ddod yn feichiog ddefnyddio dull atal cenhedlu effeithiol yn ystod yr astudiaeth hon neu am

gyfnod diogelwch o bum mis ar ôl y pigiad olaf. Dylai unrhyw ferch sy'n darganfod ei bod yn feichiog wrth gymryd rhan yn yr astudiaeth roi gwybod ar unwaith i'w meddyg ymchwil.
Nid yw'n hysbys a fydd meddyginiaeth yr astudiaeth yn effeithio ar sberm neu semen ac felly ni ddylech genhedlu plentyn yn ystod yr astudiaeth hon neu am gyfnod diogelwch o bum mis ar ôl y pigiad olaf.
Os gallai'ch partner ddod yn feichiog mae'n rhaid i chi ddefnyddio ffurfiau dibynadwy o atal cenhedlu yn ystod y treial ac am bum mis wedyn. Os bydd eich partner yn dod yn feichiog yn ystod yr astudiaeth neu o fewn pum mis i roi'r gorau i driniaeth, dylech roi gwybod i'ch meddyg astudiaeth ar unwaith. Os byddwch chi neu'ch partner yn dod yn feichiog yn ystod y treial, bydd yr angen am oruchwyliaeth feddygol ychwanegol yn cael ei thrafod â chi.

Beth ydi buddion posibl cymryd rhan?

Byddwch yn derbyn triniaeth ffisiotherapi yn ogystal â'r pigiadau, ar gyfer eich poen sciatig. Yn aml bydd ffisiotherapi'n cael ei ddefnyddio ar gyfer cleifion â chlunwst a cheir tystiolaeth i awgrymu ei fod yn helpu nifer ohonynt. Rydym yn gobeithio y byddwch yn cael budd o'r driniaeth ffisiotherapi. Nid ydym yn gwybod a fyddwch yn cael budd o'r pigiadau, ond rydym yn gobeithio y bydd y wybodaeth a gawn trwy ganlyniadau'r treial yn helpu i wella'r opsiwn triniaeth ar gyfer cleifion â chlunwst

Beth arall dylwn i wybod am adalimumab?

Argymhellir eich bod yn cludo cerdyn rhybudd therapi biolegol, a gallwch gael un o'r rhaid oddi wrth eich meddyg neu nyrs rhiwmatoleg. Yna os byddwch yn teimlo'n sâl, bydd unrhyw un sy'n eich trin yn gwybod eich bod ar y treial SCIATiC ac felly eich bod mewn perygl o'i sgil-effeithiau, gan gynnwys heintiau.

Alla i gymryd meddyginiaethau eraill ochr wrth ochr ag adalimumab?

Gellir rhoi adalimumab ar bresgripsiwn ochr wrth ochr â chyffuriau eraill. Dylech drafod unrhyw feddyginiaethau newydd â'ch meddyg cyn cychwyn arnynt, a dylech bob amser rhoi gwybod i unrhyw feddyg arall sy'n eich trin eich bod ar adalimumab. Dylech hefyd fod yn ymwybodol o'r pwyntiau canlynol:

- Nid cyffur lleddfu poen mo adalimumab. Os ydych eisoes yn cymryd cyffuriau lleddfu poen neu feddyginiaeth wrthlidiol, gallwch barhau i gymryd y rhain yn ogystal ag adalimumab, oni bai bod eich meddyg yn rhoi cyngor gwahanol. Os bydd

adalimumab yn gweithio i chi, efallai y byddwch yn gallu lleihau cyffuriau lleddfu poen neu wrthlidiol ar ôl cyfnod.

- Peidiwch â chymryd paratoadau dros y cownter neu feddyginiaethau llysieuol heb drafod hyn yn gyntaf â'ch ffisiotherapydd ymchwil, nyrs rhiwmatoleg neu fferyllydd.

Beth os bydd yna broblem?

Os oes gennych bryder ynglŷn ag unrhyw agwedd ar yr astudiaeth hon, dylech siarad ag un o'ch tîm astudiaeth lleol neu â threfnwyr y treial. Prif Ymchwilydd yr holl astudiaeth yw Dr Nefyn Williams. Prif Ymchwilydd canolfan Gogledd Cymru yw'r Athro Clare Wilkinson. Os credwch eich bod wedi dioddef niwed neu esgeulustod, gallwch gwyno trwy weithdrefn gwyno eich ysbyty lleol neu efallai y bydd gennych sail i ddwyn achos cyfreithiol yn erbyn noddwr y treial sef Prifysgol Bangor.
Rhoddir gwybodaeth fanwl am hyn yn Rhan 2.

A fydd y ffaith fy mod yn cymryd rhan yn yr astudiaeth hon yn cael ei chadw yn gyfrinachol?

Bydd yr holl wybodaeth a gesglir yn yr astudiaeth hon yn cael ei chadw'n hollol gyfrinachol. Aelodau o'r tîm ymchwil yn unig fydd yn cael mynediad ati. Bydd pob unigolyn sy'n rhoi cydsyniad i gymryd rhan yn y treial yn cael cod unigryw felly ni fydd unrhyw enwau neu fanylion sy'n galluogi adnabod unigolion penodol yn cael eu defnyddio ar holiaduron neu'n cael eu cynnwys mewn unrhyw adroddiadau astudiaeth. Mae hyn yn golygu bod y data yn ddienw. Os byddwch yn rhoi cydsyniad i gymryd rhan yn yr ymchwil, efallai y bydd personél yr ysbyty neu'r Prif Ymchwilydd neu ei enwebai, yn archwilio eich cofnodion meddygol ar ran Noddwr y treial sef Prifysgol Bangor at ddibenion dadansoddi'r canlyniadau. Rhoddir gwybod i'ch meddyg teulu, â'ch cydsyniad eich bod yn dymuno cymryd rhan mewn astudiaeth glinigol

Mae hyn yn cwblhau Rhan 1. Os oes gennych ddiddordeb yn yr astudiaeth, darllenwch y wybodaeth ychwanegol yn Rhan 2 cyn gwneud unrhyw benderfyniad.